



U.S. PHARMACOPEIA  
DRUG QUALITY AND  
INFORMATION PROGRAM

# **Rapid Assessment of Medicines Quality Assurance and Medicines Quality Control**

March 2007

## **Rapid Assessment of Medicines Quality Assurance And Medicines Quality Control**

Problems related to the quality and safety of medicines are becoming an increasing concern in many places around the world, especially in developing countries. Adequate medicines legislation and regulations, competent medicines regulatory authority (MRA), and appropriate medicine information are required to ensure the safety, efficacy, and high quality of medicines.

Legal structures are the foundation of medicines regulation. In some countries, medicines laws may not cover certain aspects of pharmaceutical activity. For example, the production of certain medicines for domestic use may not require compliance to good manufacturing practices or clinical study data may not be mandatory requirements for medicines registration. Many MRAs do not provide documented standard procedures for registration; others do not have written guidelines and checklists for inspection. All this has resulted, among other things, in a regulatory gap and inconsistent enforcement of laws, which often leads to less clarity and a lack of coherence in the medicines regulatory process.

All medicines regulatory authority functions must work in concert in order to provide effective public health protection. Key functions are licensing, product quality assessment and registration, inspection of manufacturing facilities and supply channels, laboratory control, and post-marketing surveillance for quality, adverse drug reactions, and control of promotion and advertisement of pharmaceuticals.

### **Objectives of the Assessment**

The objectives of assessing a country's medicines quality assurance and control are:

- To determine whether or not a functional and operational MRA exists in country
- To examine what approaches and mechanisms the country uses to ensure the quality of pharmaceuticals sold there and, if an MRA exists, how it carries out its responsibilities
- To identify strengths and weaknesses of the country's medicines QA program and quality control (QC) systems and the reasons for them
- To make suggestions and, where appropriate, recommendations to policymakers, decision-makers, and authorities responsible for designing and developing appropriate medicines QA/QC systems adaptable to their political and socioeconomic conditions

### **Methodology**

#### **Methodological framework**

The methodology of this assessment is based on the following framework (see Figure 12.1):

**Pre-marketing quality assessment**, which includes the assessment of medicinal drug product quality, safety, and efficacy for registration or market authorization.

**Regulatory functions**, which cover central administration (allowing the functioning of a regulatory authority), quality control or testing, inspection services, licensing of persons and pharmaceutical establishments, and product recall.

**Technical elements**, which address norms, standards, specifications and procedures, and good practices.

**Post-marketing surveillance**, which covers monitoring for medicines quality and adverse reactions, and control of medicines promotion and advertising. Figure 12.1 also illustrates the framework for data collection and the focus areas for assessment of the structural components of medicines quality assurance.

Figure 1: Framework indicating key components of a medicines quality assurance

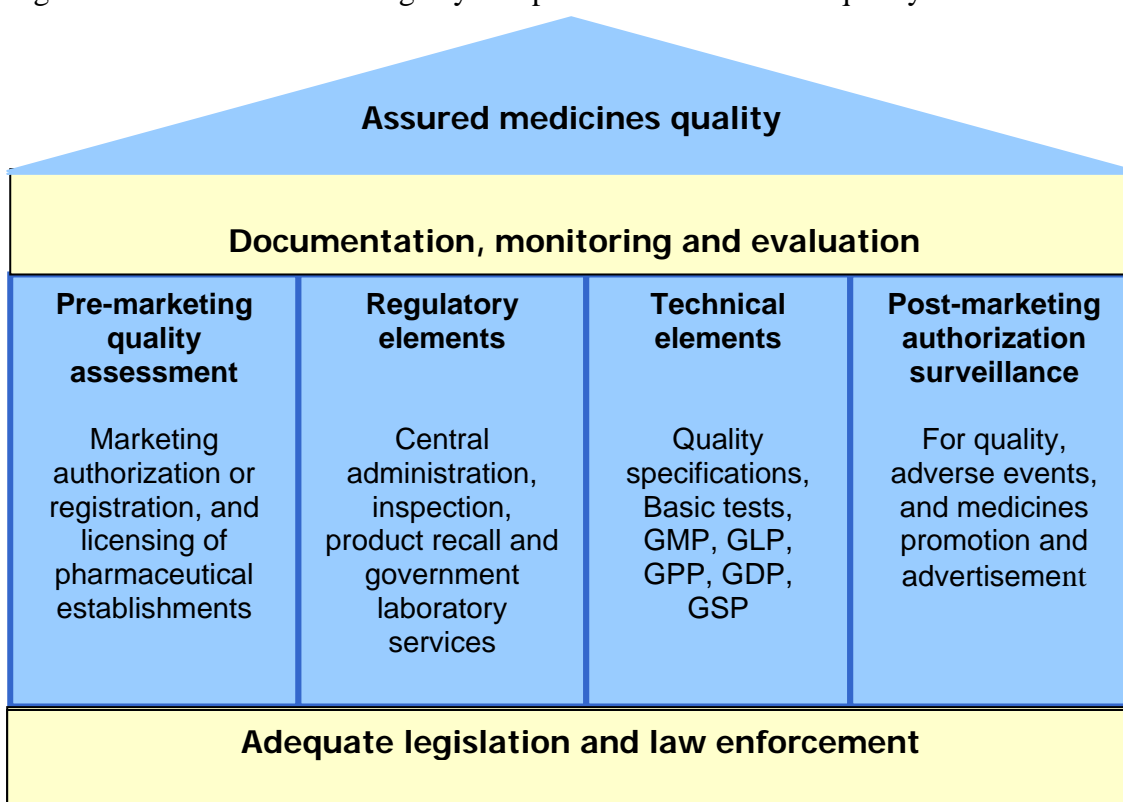


Figure 1 also illustrates the framework for data collection and the focus areas for assessment of the structural components of drug quality assurance.

### Assessment process

The process through which a nation’s MRA can develop a medicines quality assurance program and quality control system has four steps.

1. Planning for assessment
2. Data collection
3. Data analysis
4. Reporting and recommendations.

## **PLANNING FOR ASSESSMENT IN THREE STEPS**

1. Set up an Assessment Team or Working Group. The planning usually starts with establishment of an independent assessment team or assessment working group with defined role and scope of work. The team should consist of a team leader and two experienced professionals—one in pharmaceutical technical and regulatory affairs, and one in health and medicine policy analysis. To reduce the potential bias in the process while ensuring transparency and avoiding potential conflict of interest, the assessment should be carried out by a non-governmental organization (e.g., an academic institution such as university or a private organization). It can also be performed by an international organization.

It is essential that the assessment, including the appointment of the team and its role and scope of work, is approved by the relevant authority. In many instances, the Ministry of Health or MRA is the responsible body to approve it. This approval should be secured before any activities of the actual assessment begin.

2. Secure a financial budget based on the scope of work and time frame described in the assessment.
3. Communicate information about the assessment to all agencies, responsible authorities, and interested persons to enlist their support and cooperation. These usually include different units or divisions of the MRA (e.g., drug registration, inspection, licensing, laboratory testing, and post-marketing surveillance) and key players in pharmaceutical services (e.g., procurement agents, importers, wholesalers or distributors, manufacturers, and medicines regulators).

## **DATA COLLECTION METHODS AND TECHNIQUES**

A predefined indicatory questionnaire may be used to guide reviewers through collection of the data and the information required for the review and assessment (see Form 12.1). Data collection may be carried out using a combination of techniques:

- Conducting formal or semiformal discussions and consultations with key officials, to include directors or deputies of chief divisions within the MRA, government, and other procurement agencies, selected key nongovernmental organizations, drug testing laboratories, and selected key pharmaceutical establishments
- Studying and reviewing relevant and accessible (both published and unpublished) technical documents and records from primary and secondary sources. These include medicines laws, executive orders, inspection records, MRA and national laboratory annual or midterm reports, and economic, health and medicine-related indicators
- Using other convenient techniques, such as email, fax, and telephone.

## METHODS FOR DATA ANALYSIS

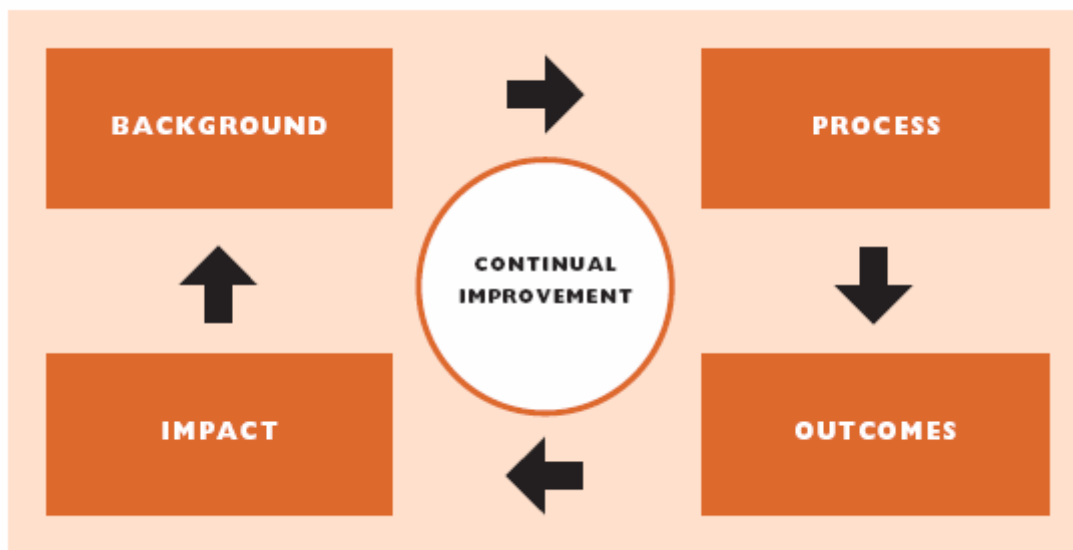
Quantitative data collected for each question in the questionnaire or obtained from other techniques may be examined, analyzed, and computed into percentages (if appropriate) by experts in the field. Where necessary and appropriate, these data can be tabulated and presented in graphs for better presentation purposes.

Relationships between certain constructs of data may be identified to find possible explanations for evaluation of a medicines regulatory system technical and managerial capability and, possibly, system performance.

Each relevant data set or construct representing each aspect of the country's medicine quality assurance and control framework—including pre-marketing quality assessment, regulatory functions performance, technical components, and post-marketing surveillance—may be analyzed and used to explain “how” and “why” each aspect works or does not work.

The analysis may be based on the principles shown in Figure 12.2 and as presented in the following structure:

Figure 12.2. Data analysis framework



**Background.** General background information on demographic, economic, health, and pharmaceutical context (with key indicators on health and pharmaceutical services of both public and private sectors, medicine regulatory system, medicines quality assurance and control) of the country being reviewed. More specifically, data and information on medicines regulatory functions and responsibilities will be added.

**Process.** The mechanisms and activities by which an MRA performs. Process indicators are used to assess the effectiveness of these mechanisms and activities, particularly, legislation, regulation and enforcement of drug laws (if any), selection and registration of essential med-

icines, and human and financial resource allocation for various medicine regulatory activities (e.g., product quality assessment, registration, inspection, testing, and continuing education).

**Outcomes.** The achievement of common objectives of each country's MRA to address poor-quality medicines in general and, in some cases, focus the assessment on particular disease programs (e.g., medicines to treat malarial or tuberculosis). Outcome indicators would be used to demonstrate the degree to which these objectives are being met.

**Impact.** The overall impact of the QA/QC activities on the national priority disease programs (e.g., reduction of poor-quality medicines over time and an increased budget allocation by the government for QA/QC work).

**Continual improvement.** The overall goal for the government (including Ministry of Health, medicines regulatory authority, disease control programs, the national laboratory for medicines quality control) and others to achieve.

It is reasonable to assume that if good results are achieved from process indicators, the outcome indicators should also show positive results or improvement over time. If the outcome indicators suggest significant problems when the structural and process indicators indicate good results, however, policymakers and regulators should investigate the problems, identify causal factors, and revise strategies accordingly.

### REPORTING AND RECOMMENDATIONS

The report of the assessment should be based on the findings of data analysis as described in the previous section and should be presented in an appropriate format for easy comprehension and quick action. Main findings and appropriate actions recommended should be included in the report, as should key issues and problematic areas of the QA/QC systems to be addressed. In the recommendations, prioritization of issues and problems to be addressed or areas of strengthening due to the lack of resources or budgetary constraints is critical. Where appropriate, a proposed step-wise process should be described.

**Form 12.1. Information Collection Questionnaire**

This questionnaire serves as a guide to obtaining general information and specific data for the review and assessment of a medicines quality assurance program and medicines quality control system. It is organized into four major categories based on the methodological framework described above.

Every effort has to be made to obtain the most up-to-date data and information. If multi-year data are involved, indicate the year next to the data. The names of interviewees or informants should be kept anonymous. The questionnaire consists of three parts:

1. Background information (e.g., country information and demographic, socioeconomic, health, and pharmaceutical data)
2. Pre-marketing quality assessment
3. Regulatory functions.

**Background Information (Indicate the year the data was collected)**

1. Country information
  - a. Area in square kilometers: \_\_\_\_\_
  - b. Administrative divisions (number of provinces, states, districts) \_\_\_\_\_  
\_\_\_\_\_
2. Demographic and socio-economic data
  - a. Total population: \_\_\_\_\_
  - b. Population distribution (urban vs. rural) \_\_\_\_\_
  - c. Life expectancy (male/female) \_\_\_\_\_
  - d. Literacy rate \_\_\_\_\_
  - e. Gross domestic product per capita (year) \_\_\_\_\_
3. Health and health system data. Indicate the year for which the data apply \_\_\_\_\_
  - a. Infant mortality rate (per 1000 live births) \_\_\_\_\_
  - b. Maternal mortality rate (per 100,000) \_\_\_\_\_
  - c. Total government health expenditure \_\_\_\_\_
  - d. Total value of international aid for health sector \_\_\_\_\_
  - e. Total number of health facilities both public and private (provide data in Table below)

Health Facilities	Government/Public	Private
Central or major hospitals		
Provincial or State		
District		
Health Center		

4. Pharmaceutical sector data. Indicate the year for which the data apply \_\_\_\_\_
  - a. Total government expenditure on medicines \_\_\_\_\_
  - b. Per capita expenditure on medicines \_\_\_\_\_

- c. Total value of domestic pharmaceutical production \_\_\_\_\_
- d. Total value of imports of finished drug products \_\_\_\_\_
- e. Total value of imports of APIs \_\_\_\_\_
- f. Total value of exports of finished drug products \_\_\_\_\_
- g. Total value of exports of APIs \_\_\_\_\_

5. Country health and pharmaceutical human resources

Description		Year
Type and number of health professional training schools		
	Medical	
	Pharmacy	
	Others, e.g., dentistry, nursing	
Number of health professionals		
	Total number of medical doctors	
	Total number of pharmacists	
	Total number of nurses	

6. Country pharmaceutical sector status (specify year)

No. of establishments	Government	Private	Others	Year
Pharmaceutical manufacturing plants				
	For APIs			
	For finished dosage forms			
	For packaging finished dosage forms			
Research-based pharmaceutical industry				
Generic (incl. branded) pharmaceutical product manufacturers				
Pharmaceutical importers				
Pharmaceutical exporters				
Pharmaceutical wholesaler or distributors				

7. Evolution of drug regulation

- a. Existence of a drug law<sup>1</sup>    yes \_\_\_\_\_    No \_\_\_\_\_    If yes, provide answers to questions b, c, and d below.
- b. The year when the drug law or regulation was first introduced \_\_\_\_\_

<sup>1</sup> The names of the law might vary from one country to another, e.g., some call drug law, others call pharmaceutical management law, etc.

Rapid Assessment of Medicines Quality Programs

- c. The title of the first law/act/regulation enacted \_\_\_\_\_  
 \_\_\_\_\_
- d. Which of the following aspects of drug quality, safety, efficacy are covered by present drug law(s) or regulations:
- Drug product registration – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Pharmaceutical establishment licensing – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Control of drug importation – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Control of drug exportation – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Inspection services – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Monitoring for quality and ADR – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Control of drug promotion and advertising – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Drug quality testing/control – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Control of clinical trials – Yes\_\_\_\_\_ No\_\_\_\_\_
  - Others (specify) – \_\_\_\_\_

- e. Existence of national medicines policy: Yes\_\_\_\_\_ No\_\_\_\_\_
- If yes, indicate the year of its promulgation or introduction: \_\_\_\_\_
- What are the main components of the policy? \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

- f. Existence of national regulatory agency or authority: Yes\_\_\_\_\_ No\_\_\_\_\_
- If yes, describe its key functions:
- \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_

8. Government budget allocations for drug regulatory affairs/activities: Has the government budget increased over the last three years?  
 Yes\_\_\_\_\_ No\_\_\_\_\_

If yes, provide approximate figures in the following table.

Year	Government budget figure in US\$
Current year:	
Last year:	
The year before	
Etc.	

If no, provide reasons, e.g., introduction of cost-recovery scheme or charge of fees for services, etc.

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## Pre-Marketing Quality Assessment and Registration<sup>2</sup>

1. Existence of drug product assessment/evaluation unit/team for registration within the national medicines authority. Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, what aspects of the following the unit/team assesses:  
 Quality       Safety       Efficacy       Cost-effectiveness
  
2. Present number of officers/professionals responsible for routine drug registration within the MRA: \_\_\_\_\_  
And their professional qualifications: \_\_\_\_\_  
\_\_\_\_\_
  
3. Existence of standard operating procedures (SOPs) for drug product registration:  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, ask him/her to produce the SOP documents and record their titles below:  
\_\_\_\_\_  
\_\_\_\_\_
  
4. In addition to the MRA staff persons in this unit/team, is there medicines evaluation committee consisting of appointed members from relevant disciplines whose role is making decision on product registration?  
Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, check the appropriate boxes below:  
 a clinician from a major teaching hospital  
 a pharmacologist from teaching institution or major hospital  
 a regulatory personnel from the national MRA  
 a general or community practitioner  
 a community pharmacist  
 a manufacturing or GMP expert  
 a pediatrician, and  
 a representative from consumer associations.
  
5. What key information is required for the registration? Check appropriate boxes that apply.  
 Applicant information     Manufacturer information  
 Product information which should include in the application/dossier:  
 Intended marketed name  
 Detailed formulation (e.g., dosage, form, strength, name and content of each ingredients, therapeutic indication)  
 Complete batch manufacturing record

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<sup>2</sup> Product market authorization is also used instead of product registration

## Rapid Assessment of Medicines Quality Programs

- Packaging material
- Labeling detailed information
- The product registration status in other countries
- Stability study data
- Bioavailability/bioequivalence data
- Clinical trials data

6. Do the same requirements apply for both branded/innovative and generic pharmaceutical preparations? Yes \_\_\_\_\_ No \_\_\_\_\_. If no, explain what requirement(s) is (are) different? \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

7. How much does it cost the applicant to apply, renew, or change of application for a medicine product for human use registration?

Description	US\$
Application for registration of new branded/innovative product	
Application for registration of a generic product	
Application for change of application	
Application for renewal	

8. Is there a specific budget for drug registration: Yes \_\_\_\_\_ No \_\_\_\_\_  
 If yes, please specify sources: Government \_\_\_\_\_ (year: \_\_\_\_\_)  
 Fees charged from services \_\_\_\_\_ (year: \_\_\_\_\_)

9. Number applications received by MRA in the last three years:

Description	Number		
	Specified year		
Total number of applications received			
- Application for registration of new branded/innovative product			
- Application for registration of a generic product			
- Application for change of application			

10. Number of registration certificates issued, renewed, suspended, or revoked in the last three years?

Description	Year:	Year:	Year:
Total number issued			
Total number renewed			
Total number suspended			
Total number revoked			
Total number under consideration/investigation			
Total number not-yet evaluated			

11. Total up-to-date number of pharmaceutical product preparations for human use officially registered in the country \_\_\_\_\_(year) \_\_\_\_\_  
Of which \_\_\_\_\_are generic products (including branded generic)
12. Estimated total number of unregistered pharmaceutical product preparations for human use available in the country \_\_\_\_\_(year) \_\_\_\_\_
13. Does the country allow the import of unregistered pharmaceutical products?  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, please briefly explain under what circumstances, e.g., donated medicines or emergency: \_\_\_\_\_
14. Registration validation is for:     2 years  
   3 years  
   4 years  
   5 years  
   > 5 years
15. Lead time (i.e., average time span between application submission and the date of issuance of the registration certificate) taken for registering a pharmaceutical product.  
 < 6 Months     6- 12 months     1- 2 years     > 2 years
16. Existence of fast-track registration system: Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, indicate conditions or requirements for a product to be eligible for fast-track registration:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
17. Are guidelines or instructions on drug product registration available and freely accessible:  
Yes \_\_\_\_\_ No \_\_\_\_\_. If yes, they are available  
 On the Internet or World Wide Web, specify the URL address:  
\_\_\_\_\_  
 In hard copies only
18. Current registration system:  
 Manual (or with MS excel software)  
 Computer-assisted, specify the software being used \_\_\_\_\_

**Regulatory Functions**

(Central administration: Allows the functioning of regulatory authority, quality control, inspection services, control of pharmaceutical promotion, advertising, and recall).

**A. Central Administration**

19. Existence of a central administration office that oversees key pharmaceutical activities and functions (product assessment and registration, licensing of persons and pharmaceutical establishments or premises, inspection, development and implementation of technical requirements, advertisement and promotion, and post-marketing surveillance):

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, name it \_\_\_\_\_

20. Professional qualifications of director and deputy directors.

Description	Number	Qualification or professional title	Remarks
Director			
Deputy director(s)			

21. Professional qualifications and the number of people working at central administration; provide year when data/information is obtained \_\_\_\_\_

Qualification	Pharmacy/ pharmaceutical sciences	Medical sciences	Other disciplines
Post-graduates			
Graduates			
Technicians			
Other (specify)			
Total			

22. Professional qualifications and the number of people working in the following functions at MRA; provide year when data/information is obtained \_\_\_\_\_

Function	Post-graduates (specify degree)	Graduates	Other (specify)
Drug product assessment and registration			
Licensing of pharmaceutical establishments or premises			
Regulation and inspection			
Medicines advertisement and promotion			
Post-marketing surveillance			
Other (specify)			

**B. Licensing of Persons, Pharmaceutical Establishments, or Both**

23. Existence of unit/team in charge of issuing, variation, suspension, and revocation of license for persons or pharmaceutical establishments. Yes\_\_\_\_\_ No\_\_\_\_\_

24. Number of officers/professionals responsible for routine licensing: \_\_\_\_\_  
 Their professional qualifications: \_\_\_\_\_  
 \_\_\_\_\_

25. Is the national MRA the only agency that issues the licenses for persons or pharmaceutical establishments in the country?  
 Yes\_\_\_\_\_ No\_\_\_\_\_. If no, please specify if the provincial or state authority also issues licenses for those establishments operating at provincial/state level:  
 \_\_\_\_\_  
 \_\_\_\_\_

26. Existence of standard operating procedures (SOPs) for licensing of persons or pharmaceutical establishments: Yes\_\_\_\_\_ No\_\_\_\_\_   
 If yes, ask for titles of the documents of SOPs: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

27. What key professional qualifications are required to obtain a license to engage in or operate the following pharmaceutical activities?

Practice/activity	Professional requirement
Manufacturing	
Importing/exporting	
Wholesaling	
Retail selling/pharmacy	

28. For retail pharmacy outlets, what are the key regulatory requirements to be met for license approval? Check all boxes that apply.

- specified location e.g. based on population heads
- specified list of medicines to abide with for sale
- completion of certified pharmacy or dispensing training program
- other(s)\_\_\_\_\_

29. Number of manufacturer/producer licenses issued, renewed, suspended, or revoked in the last three years?

Description	Year:	Year:	Year:
Total number issued			
Total number renewed			
Total number suspended			
Total number revoked			
Total number under consideration/investigation			
Total number not-yet assessed			

Rapid Assessment of Medicines Quality Programs

30. Is pre-qualified inspection for GMP compliance of the manufacturing site a pre-condition for licensing of a manufacturing plant?

Yes \_\_\_\_\_ No \_\_\_\_\_

31. Number of wholesaler/distributors/importers and exporters licenses issued, renewed, suspended, or revoked in the last three years?

Description	Year:	Year:	Year:
Total number issued			
Total number renewed			
Total number suspended			
Total number revoked			
Total number under consideration/investigation			
Total number not-yet assessed			

32. What are the main requirements and qualifications to be met for license approval of a pharmaceutical wholesaler or distributor?

- in compliance with regulatory requirements e.g. based on outcomes of the inspection
- specified location
- professional qualification – e.g., pharmacist as technical manager
- adequate facility with proper air ventilation and air conditioning
- appropriate storage areas (cold, cool, and room temperature rooms)
- at least 80% of the transport means are in good working conditions
- other(s) \_\_\_\_\_

33. Number of retailed pharmacies (of all categories, if different) licenses issued, renewed, suspended, or revoked in the last three years?

Description	Year:	Year:	Year:
Total number issued			
Total number renewed			
Total number suspended			
Total number revoked			
Total number under consideration/investigation			
Total number not-yet assessed			

34. Estimated total number of illegal (or unlicensed) pharmaceutical establishments preparations for human use that engaged in the manufacture, import, export, or retail sale of pharmaceutical products in the country. Check all boxes that apply.

Description	Year:	Year:	Year:
Manufacturer/producer			
Wholesaler/importer/exporter			
Retail pharmacy			

35. A license validation applied to the following establishments

Description	2 years	3 years	4 years	5 years	> 5 years
Manufacturer/producer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Wholesaler/importer/exporter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Retail pharmacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

36. Lead time (i.e., average time span between application submission and the date of issuance of the license) taken for a license of a retail pharmacy.

- < 6 Months       6- 12 months       1- 2 years       > 2 years

37. Are guidelines or instructions on retail pharmacy licensing available and freely accessible: Yes \_\_\_\_\_ No \_\_\_\_\_. If yes, they are available

- On the Internet or World Wide Web, specify the URL address:

\_\_\_\_\_

- In hard copies only

38. Does the MRA apply fees for service to the applicant of an application to obtain a license to operation a pharmaceutical establishment? Yes \_\_\_\_\_ No \_\_\_\_\_. If yes, provide more information in table below:

Type of license	Approx. fees charged	Remarks
Manufacturing pharmaceutical product		
Wholesaling/distributing		
Importing/exporting		
Retail pharmacy		

39. In addition to the MRA staff persons in charge of licensing, is there an advisory or expert committee consisting of appointed members from relevant agencies whose role is making decision on licensing?

Yes \_\_\_\_\_ No \_\_\_\_\_. If yes, check the appropriate boxes below:

- National MRA  
 Local authority  
 Professional association  
 Others, specify \_\_\_\_\_

**C. Laboratory Control and Testing**

40. Existence of a national medicines quality control laboratory (NMQCL)

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, obtain the following data and information:

Number and name of each unit or division of the Lab:

Number of units/divisions: \_\_\_\_\_

- Name of each unit/division: a. \_\_\_\_\_  
 b. \_\_\_\_\_  
 c. \_\_\_\_\_  
 d. \_\_\_\_\_

Rapid Assessment of Medicines Quality Programs

- e. \_\_\_\_\_
- f. \_\_\_\_\_
- g. \_\_\_\_\_

41. Professional qualification and the number of people working at NMQL – provide year when data/information is obtained \_\_\_\_\_

Qualification	Pharmacy/ pharmaceutical sciences	Chemistry	Other, specify
Post-graduates			
Graduates			
Technicians			
Other (specify)			

42. Types of tests or assays the laboratory can perform for pharmaceutical compounds:

- a. Identification of APIs Yes \_\_\_\_\_ No \_\_\_\_\_
- b. Hardness (for solid form) Yes \_\_\_\_\_ No \_\_\_\_\_
- c. Loss on drying Yes \_\_\_\_\_ No \_\_\_\_\_
- d. Melting range Yes \_\_\_\_\_ No \_\_\_\_\_
- e. Residue on ignition Yes \_\_\_\_\_ No \_\_\_\_\_
- f. Disintegration Yes \_\_\_\_\_ No \_\_\_\_\_
- g. Dissolution Yes \_\_\_\_\_ No \_\_\_\_\_
- h. Assay for content of API(s) Yes \_\_\_\_\_ No \_\_\_\_\_
- i. Any of the following special tests:
  - Sterility Yes \_\_\_\_\_ No \_\_\_\_\_
  - Pyrogen Yes \_\_\_\_\_ No \_\_\_\_\_
  - Bacterial endotoxin Yes \_\_\_\_\_ No \_\_\_\_\_
  - Bioavailability Yes \_\_\_\_\_ No \_\_\_\_\_
  - Bioequivalence Yes \_\_\_\_\_ No \_\_\_\_\_
  - Impurities (ordinary impurities) Yes \_\_\_\_\_ No \_\_\_\_\_
  - Water content Yes \_\_\_\_\_ No \_\_\_\_\_
  - Heavy metals Yes \_\_\_\_\_ No \_\_\_\_\_
  - Other (specify) \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_

42. Existence of a national pharmacopeia: Yes \_\_\_\_\_ No \_\_\_\_\_  
 If yes, provide name, year first published, and current edition  
 \_\_\_\_\_

43. Name of pharmacopeias officially accepted for use in the country:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_



Rapid Assessment of Medicines Quality Programs

47. Specify the most common medicines groups (e.g., antibiotic, antipyretic, anti-inflammatory, etc.) that the lab has tested in the last 3 years:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

48. Sources that have sent medicines samples or APIs and requests for tests:

- e.g., inspection unit of MRA
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

49. Purposes for quality testing of medicines samples in the last two years:

Purpose	No. and year:	No. and year:
Registration		
Quality monitoring		
Manufacturing (in process control)		
Request from pharmaceutical company		
Request from individuals		
Administrative or regulatory action		
Other (specify)		

50. Does the lab charge fees for testing services? Yes\_\_\_\_\_ No\_\_\_\_\_   
 If yes, indicate the average fees the lab charges per sample testing using pharmacopeial method:\_\_\_\_\_ USD

51. Total annual budget for the lab operation including salaries of staff \_\_\_\_\_ USD (year\_\_\_\_\_)

52. Total annual budget for the lab equipment/instrument maintenance \_\_\_\_\_ USD (year\_\_\_\_\_)

53. Major sources of budget for the lab operations/activities, specify:  
 Government  
 Fees for services  
 Donation, including grants and aides, if this box is checked, go to Question 54.

54. Has the lab received any financial or in-kind support from any international agencies since its establishment?

If yes, indicate estimated value or type of equipment and year of support:  
 ▪ \_\_\_\_\_ present year\_\_\_\_\_

- \_\_\_\_\_ year \_\_\_\_\_
- \_\_\_\_\_ year \_\_\_\_\_
- \_\_\_\_\_ year \_\_\_\_\_
- \_\_\_\_\_ year \_\_\_\_\_

55. Main constraints faced in conducting the various tests/assays in the Lab. Check all boxes that apply:

- Financial constraints – low government budget
- Limited numbers of qualified professionals
- Lack of continuing education/training
- Limited number of adequate lab equipment/instrument
- Unavailability of certain reference standards/substances
- Unavailability of pharmacopeial specifications or methods
- Unavailability of certain reagents, solvents, and indicators
- Other (specify) \_\_\_\_\_  
\_\_\_\_\_

56. Laboratory management with regard to some aspects of Good Laboratory Practices.

Check all boxes that apply:

- Existence and use of sample receiving/collection notebook
- Existence and use of laboratory notebook
- Existence and use of analytical work book or work sheet
- Existence and use of lab equipment log book
- Existence (in written document) of safety rules and measures applied
- Existence and use of appropriate lab clothes, gloves, goggles, etc.
- Existence and use of appropriate and separate storage room for reference substances, toxic and poisonous materials, and inflammable chemicals.
- Working reagents, references, solutions, solvents, and samples are appropriately labeled (at least their name, concentration, date of preparation, initial of preparator, count, as necessary)
- Existence and use of standard operating procedures for testing and other activities
- Existence and use of air-sucking chamber
- Other \_\_\_\_\_

57. Has the lab participated in any international or regional assessment for professional and technical competency?  Yes  No. If yes, describe the event and the year:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

58. Has the lab ever been requested to test a certain product's quality by an international agency or neighboring countries? If yes, describe the event and the year:

\_\_\_\_\_  
\_\_\_\_\_

Rapid Assessment of Medicines Quality Programs

59. Has the lab received any complaints regarding its testing results in the past three years? If yes, briefly describe the event: \_\_\_\_\_  
 \_\_\_\_\_

**D. Inspection Services (GMP and Pharmaceutical Supply / Distribution Chains)**

60. Existence of provisions in the drug law/regulations defining the powers and status of GMP inspectors: Yes \_\_\_\_\_ No \_\_\_\_\_

61. Existence of a GMP inspectorate: Yes \_\_\_\_\_ No \_\_\_\_\_  
 If yes, provide more information in the table below:

Description	Number	Remarks e.g., if the same inspector performs both GMP and distribution chain
GMP inspector		
Pharmaceutical distribution chain		
Other, e.g., investigational		

62. Relationship of GMP inspector(s) to the unit/division in charge of licensing of manufacturers and product registration unit/division:  
 \_\_\_\_\_  
 \_\_\_\_\_

63. Existence of national GMP guidelines: Yes \_\_\_\_\_ No \_\_\_\_\_  
 If yes, give its name and year of introduction \_\_\_\_\_  
 \_\_\_\_\_ (year \_\_\_\_\_)

If no, what GMP guidelines (e.g. WHO, ASEAN) are officially accepted for use in the country?  
 \_\_\_\_\_

64. Existence of manuals or standard operating procedures (SOPs) for GMP inspectors:  
 Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, provide name and date of publication: \_\_\_\_\_  
 \_\_\_\_\_ (year \_\_\_\_\_)

65. Status of application of GMP guidelines/standards for manufacturing plants:  
 Voluntary \_\_\_\_\_ Compulsory (required by law) \_\_\_\_\_

66. Number of inspections carried out per year for routine GMP inspection: \_\_\_\_\_

67. Information on current GMP inspection-related activities:

No. of plants and type of inspection	Year:	Year:	Present Year:
Total No. of manufacturing plants in the country			
No. of plants inspected and compliant to GMP			

## Rapid Assessment of Medicines Quality Programs

No. of plants inspected for renewal of license			
No. of plants inspected because of complaints			
No. of plants inspected as follow-up			
Other (specify)			

68. Number of administrative and regulatory measures taken against GMP non-compliant manufacturing plants in the last three years:

Measures taken:	Year:	Year:	Present year:
Written notice of warning			
Fines			
License suspended			
License revoked			
Production suspended			
Other (specify)			

69. Existence of plan to increase number of manufacturing plants to comply with GMP standards: Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, indicate target number by year:

Current target to increase GMP compliance:	Current year:	Year:	Year:
No. of GMP noncompliant manufacturing plants			
No. of GMP compliant plants			

70. Inspections in the drug supply/distribution chain – existence of inspection services in the drug supply chain: Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, indicate number of inspections per year planned: \_\_\_\_\_

71. Are medicines samples collected by the inspector(s) during inspections?  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, provide information below:

Samples collected and tested in connection with:	No. of samples collected	Passed quality testing	Failed quality testing
	Year:	Year:	Year:
GMP inspection			
Distribution chain inspection			
Other (specify)			
Total			

72. Number of administrative and/or regulatory measures taken against practices related to producing and/or selling poor quality products in the last three years:

Measures taken:	Year:	Year:	Year:
Written notice of warning to manufacturer,			

Rapid Assessment of Medicines Quality Programs

wholesaler, and retailer			
Fines			
License suspended			
License revoked			
Pharmaceutical product recall by MRA			
Pharmaceutical product withdrawal by the distributor or producer			
Other (specify)			

73. Does MRA charge fees for inspection services for both GMP and distribution chain?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, indicate rough fees charge for the type of inspection in the table below:

Type of inspection	Fees charges applied, in US\$		
	Per hour	Per day	Per plant facility
GMP			
Distribution chain			

74. Existence of mechanism or system for monitoring of quality of medicines as post-marketing surveillance activity: Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, briefly describe the mechanism \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

75. Existence of product quality and adverse drug reactions reporting mechanism or system:

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, briefly describe the mechanism \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

76. Existence of product recall mechanism or system: Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, briefly describe the mechanism \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

77. Main constraints faced in carrying out inspection services.

Check all boxes that apply:

- Financial constraints – low government budget
- Limited numbers of qualified inspectors
- Lack of continuing education/training
- Lack of SOP or guidelines
- Limited access to relevant information on inspection

Other (specify) \_\_\_\_\_  
 \_\_\_\_\_

**E. Other Relevant Questions** – pose to key stakeholders, e.g., drug outlets, distributors/importers/wholesalers, and manufacturers during the visit to their premises. the data collection team should be accompanied by the relevant authority (e.g., drug regulatory agency personnel) to visit the premises.

**78. Retail drug outlets or pharmacies**

- a. Is the premise operating under a valid license, i.e., has it been licensed by the relevant drug authority and is the license still valid?  
 Yes     No
  
- b. Is the outlet attendant the person who holds the license?  
 Yes     No
  
- c. What are main sources of the medicines sold in the outlet?  
*Check all that apply:*
  - direct from local manufacturing companies
  - from main domestic wholesaler(s)
  - other sources \_\_\_\_\_
  
- d. Has the outlet kept all documents or papers, such as invoices, that can be used to trace the sources of medicines purchased?  
 Yes     No
  
- e. Any expired-date products found on the premise?  
 Yes     No
  
- f. Does the outlet have a refrigerator to store medicines requiring cold temperature?  
 Yes     No
  
- g. Have medicines been kept out of direct sunlight?  
 Yes     No
  
- h. Has the premise been inspected by the Inspector(s) from MRA?  
 Yes     No

If yes, provide the number of occasions inspected by year:

Number of inspections	Purpose of inspection	Month and Year

**79. Wholesaler/distributor**

- a. Is the company operating under a valid license, i.e., has it been licensed by the relevant drug authority and is the license still valid?  
 Yes     No
- b. What are the main sources or suppliers of the medicines sold by the wholesaler?  
*Check all that apply:*  
 direct from local manufacturing companies  
 direct from foreign manufacturers  
 from foreign or international distributors/suppliers  
 other sources \_\_\_\_\_
- c. Have the sources or suppliers of medicines pre-qualified?  
 Yes     No  
If yes, by whom?  
 national MRA  
 international agency, please name it \_\_\_\_\_
- d. Was pre- or post-shipment inspection carried out by the company before accepting any consignment?  
 Yes     No  
If yes, by whom?  
 QA/QC personnel of the company  
 national DRA official  
 sub-contracting private entity
- e. Has the company kept all documents or papers, such as invoices, which can be used to trace the sources of medicines purchased?  
 Yes     No
- f. Does the premise storage facility have cold and cool rooms?  
 Yes     No
- g. Does the storage facility have the following critical components?  
*Check all that apply:*  
 incoming medicines receiving area  
 quarantine area or room  
 (basic) laboratory testing facilities or room  
 SOPs for receiving and storing medicines  
 inventory control system (manual \_\_\_\_\_; computerized:\_\_\_\_\_)
- h. Any expired-date products found in the premise?  
 Yes     No

i. Does the premise have appropriate air ventilation and air conditioning?  
 Yes       No

j. Has your premise been inspected by the Inspector(s) from DRA?  
 Yes       No

If yes, provide the number of occasions inspected by year:

Number of inspections	Purpose of inspection	Year

k. What is your opinion of the current system of drug registration in terms of process (transparency, effectiveness), application time, availability of clear instructions, and fees:

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